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| 10/521,097 | 11/04/2005 | Ralf-Christian Schlothauer | 14923.0024 | 7026 |
| 27890 7590 01/11/2008 STEPTOE & JOHNSON LLP 1330 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036 | | | EXAMINER TONGUE, LAKIA J | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,097

Applicant(s)

SCHLOTHAUER ET AL.

Examiner

Lakia J. Tongue

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 January 1943.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 37,39 and 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36,38 and 40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 37, 39 and 41-43 are drawn to non-statutory use claims and have been withdrawn from further consideration. Claims 1-36, 38 and 40 are subject to the restriction requirement set forth below.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-22, 24, 26-29 and 32-34, drawn to a composition for consumption, said composition comprising a viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme.

Group II, claim(s) 23, 25, 30 and 31, drawn to a method of preparing a food product, the method comprising admixing a composition with another component so as to form said food product; wherein said composition is a composition for consumption, said composition comprising a viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme.

Group III, claim(s) 35, drawn to a process for producing an EPS comprising growing a lactic acid bacterium selected from the group comprising *Leuconostoc mesenteroides* spp., *Lactobacillus sake* spp., *Lactobacillus plantarum* spp. and *Lactobacillus salivarium* spp. which produce an enzyme capable of synthesizing an EPS in a commercially acceptable medium.

Group IV, claim(s) 35, drawn to a process for producing an enzyme comprising growing a lactic acid bacterium selected from the group comprising *Leuconostoc mesenteroides* spp., *Lactobacillus sake* spp., *Lactobacillus plantarum* spp. and *Lactobacillus salivarium* spp. which produce an enzyme capable of synthesizing an EPS in a commercially acceptable medium.

Group V, claim(s) 35, drawn to a process for isolating the EPS comprising growing a lactic acid bacterium selected from the group comprising *Leuconostoc mesenteroides* spp., *Lactobacillus sake* spp., *Lactobacillus plantarum* spp. and *Lactobacillus salivarium*

spp. which produce an enzyme capable of synthesizing an EPS in a commercially acceptable medium.

Group VI, claim(s) 35, drawn to a process for isolating the enzyme comprising growing a lactic acid bacterium selected from the group comprising *Leuconostoc mesenteroides spp.*, *Lactobacillus sake spp.*, *Lactobacillus plantarum spp.* and *Lactobacillus salivarium spp.* which produce an enzyme capable of synthesizing an EPS in a commercially acceptable medium.

Group VII, claim(s) 36, drawn to a process for preparing an EPS as defined in any preceding claim comprising: growing a lactic acid bacterium selected from the group comprising *Leuconostoc mesenteroides spp.*, *Lactobacillus sake spp.*, *Lactobacillus plantarum spp.* and *Lactobacillus salivarium spp.* which produce an enzyme capable of synthesizing an EPS in a commercially acceptable medium supplemented with a suitable enzyme substrate such as sucrose, lactose, raffinose, stachyose or verbascose and the acceptor molecule maltose as the only carbon source, and optionally, isolating the EPS.

Group VIII, claim(s) 36, drawn to a process for isolating an EPS comprising growing a lactic acid bacterium selected from the group comprising *Leuconostoc mesenteroides spp.*, *Lactobacillus sake spp.*, *Lactobacillus plantarum spp.* and *Lactobacillus salivarium spp.* which produce an enzyme capable of synthesizing an EPS in a commercially acceptable medium supplemented with a suitable enzyme substrate such as sucrose, lactose, raffinose, stachyose or verbascose and the acceptor molecule maltose as the only carbon source.

Group IX, claim(s) 38, drawn to a process for producing a microbial composition comprising growing *in situ* said lactic acid micro-organism in a commercially acceptable medium whereby said lactic acid micro-organism produces an enzyme capable of synthesizing an EPS.

Group X, claim(s) 40, drawn to an assay for screening a composition, said assay comprising adding a candidate composition to a food product and determining the extent of improvement in the texture, body, mouth-feel, viscosity, structure and/or organoleptic properties of food product; wherein said composition comprises a viable lactic acid bacterium, an enzyme derivable from said lactic acid bacterium and an EPS produced by said enzyme.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct microorganism, enzyme or EPS. Each organism is patentably distinct because the

organisms are of a different genus, and a further restriction is applied to each Group. Applicant must further elect a single microorganism (i.e. *Leuconostoc mesenteroides*). (See MPEP 803.04).

Additionally, if Group I-X is elected, Applicant must, in addition to the aforementioned election of a single microorganism, enzyme or EPS.

Applicant is advised that examination will be restricted to only the elected microorganism and should not be construed as a species election.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: they recite multiple products and multiple processes of using each product.

Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited **composition**. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT rule 13.2 and that each of such products and methods accordingly defines a separate invention.

The first claimed invention is drawn a composition for consumption, said composition comprising a viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme.

The special technical feature lacks novelty under PCT Article 33(2), for example, over Pailin et al. (Letters in Applied Microbiology, 2001; 33: 45-49) which discloses *Lactobacillus bulgaricus* cultures produced more extracellular cell-bound proteinase. Moreover, Pailin et al. disclose that strong positive correlations were noted between the size of the exopolysaccharide (EPS) layer and extracellular cell-bound proteinase in both *Streptococcus* and *Lactobacillus* cultures (see abstract and materials and methods).

Claim limitations such as "for consumption" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 458.

These inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; (2) a product and a process of use of said product; (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. **If multiple products,**

processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See 37 C.F.R. 1.475.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (PCT Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in PCT Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1...", or "Process for the manufacture of the product of Claim 1..."). Similarly, a claim to one part referring to another cooperating part, for example, "A plug for cooperation with the socket of Claim 1..." is not a dependent claim. See M.P.E.P. § 1850, section II.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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